10 CIV 1796

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC.,

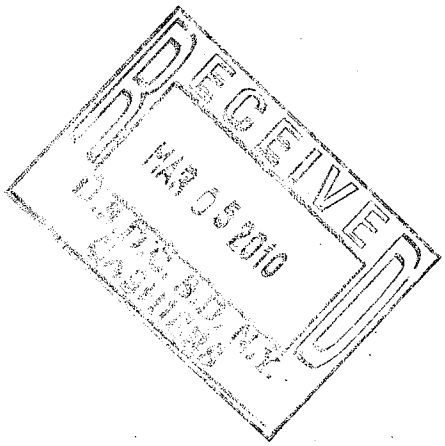
Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Case No.:



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead" or "Plaintiff") for its Complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva"), hereby allege as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, defendant Teva Pharmacuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

4. On information and belief, defendant Teva Pharmaceutical Industries, Ltd. ("Teva Industries") is an Israeli corporation having its principal place of business at 5 Basel St., P.O. Box 3190, Petach Tikva 49131, Israel.

5. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries, and these two companies have common officers and directors.

6. Upon information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, assistance of, and at least in part the benefit of, Teva Industries.

Jurisdiction and Venue

7. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, this Court has personal jurisdiction over Teva USA and Teva Industries.

9. On information and belief, Teva USA derives substantial revenue from selling various products and doing business throughout the United States, including in New York and this District.

10. On information and belief, Teva USA is registered to do business with the New York State Division of Corporations, and Corporate Creations Network Inc., 15 North Mill Street, Nyack, New York 10960 is authorized to accept service on behalf of Teva USA.

11. On information and belief, Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold, including sold by Teva USA, throughout the United States, including in this District.

12. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Background

13. Gilead is the holder of New Drug Application ("NDA") No. 21-356 which relates to tablets containing 300 mg of tenofovir disoproxil fumarate. On October 26, 2001, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-356 for the treatment of HIV-1 infection in adults. These tablets are prescribed in the United States under the trademark Viread®.

14. Gilead is the holder of NDA No. 21-752 which relates to tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On August 2, 2004, the FDA approved the use of the tablets described in NDA No. 21-752 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®.

15. Gilead is the holder of NDA No. 21-937 which relates to tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the FDA approved the use of the tablets described in NDA No. 21-

937 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Atripla®.

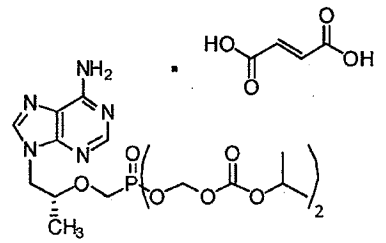
16. United States Patent No. 5,922,695 ("the '695 Patent," copy attached as Exhibit A), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the United States Patent and Trademark Office on July 13, 1999. The claims of the '695 Patent cover, *inter alia*, tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Viread®, Truvada®, and Atripla®.

17. United States Patent No. 5,935,946 ("the '946 Patent," copy attached as Exhibit B), entitled "Nucleotide analog composition and synthesis method," was duly and legally issued by the USPTO on August 10, 1999. The claims of the '946 Patent cover, *inter alia*, tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®) and its use to treat a patient infected with a virus or who is at risk of viral infection. The '946 Patent is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

18. United States Patent No. 5,977,089 ("the '089 Patent," copy attached as Exhibit C), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the USPTO on November 2, 1999. The claims of the '089 Patent cover, *inter alia*, the oral administration to a patient tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®), and is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

19. United States Patent No. 6,043,230 ("the '230 Patent," copy attached as Exhibit D), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the USPTO on March 28, 2000. The claims of the '230 Patent cover, *inter alia*, treating a patient with tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®), and is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

20. Tenofovir disoproxil fumarate is a compound that has a molecular formula of $C_{19}H_{30}N_5O_{10}P \cdot C_4H_4O_4$, and which has the following chemical structure:



TDF

21. Tenofovir disoproxil fumarate can be referred to by any of several chemical names. Tenofovir disoproxil fumarate is described in the Viread® label as "a fumaric acid salt of bis-isopropoxycarbonyloxymethyl ester derivative of tenofovir." Chemical names recited for tenofovir disoproxil fumarate in the '946 Patent are "9-[2-(R)[[bis[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]adenine.fumaric acid" and "bis(POC)PMPA fumarate."

22. The named inventors on the '695, '089, and '230 Patents are Murty N. Arimilli, Kenneth C. Cundy, Joseph P. Dougherty, Choung U. Kim, Reza Oliyai, and Valentino

J. Stella. William A. Lee was added as a named inventor to the '695, '089, and '230 Patents during their re-examination.

23. Murty N. Arimilli, Kenneth C. Cundy, Joseph P. Dougherty, Choung U. Kim, Reza Oliyai, Valentino J. Stella, and William A. Lee assigned the '695, '089, and '230 Patents to Gilead.

24. The named inventors on the '946 Patent are John D. Munger, Jr., John C. Rohloff, and Lisa M. Schultze.

25. John D. Munger, Jr., John C. Rohloff, and Lisa M. Schultze assigned the '946 Patent to Gilead.

COUNT 1
Infringement of U.S. Patent No. 5,922,695 (ANDA No. 91-612)

26. Plaintiff repeats and realleges paragraphs 1-25 above as if set forth herein.

27. On information and belief, Teva submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 91-612, to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate.

28. On information and belief, ANDA No. 91-612 seeks approval to manufacture, use, and sell tenofovir disoproxil fumarate for the purpose of treating HIV infection in adults.

29. By letter dated January 25, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 25, 2010 Viread® Notice Letter"), Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use,

and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent.

30. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-612, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '695 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '695 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

31. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-20, 22-24, and 31 of the '695 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-612.

32. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

33. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '695 Patent.

34. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '695 Patent.

COUNT 2
Infringement of U.S. Patent No. 5,935,946 (ANDA No. 91-612)

35. Plaintiff repeats and realleges paragraphs 1-25 and 27-28 above as if set forth herein.

36. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent.

37. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '946 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '946 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis

of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

38. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-612.

39. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2). .

40. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '946 Patent.

41. On information and belief, the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '946 Patent.

COUNT 3
Infringement of U.S. Patent No. 5,977,089 (ANDA No. 91-612)

42. Plaintiff repeats and realleges paragraphs 1-25 and 27-28 above as if set forth herein.

43. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent.

44. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '089 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '089 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

45. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

46. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing

300 mg of tenofovir disoproxil fumarate, before the '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

47. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '089 Patent.

48. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '089 Patent.

COUNT 4
Infringement of U.S. Patent No. 6,043,230 (ANDA No. 91-612)

49. Plaintiff repeats and realleges paragraphs 1-25 and 27-28 above as if set forth herein.

50. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent.

51. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '230 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '230 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this

application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

52. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

53. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '230 Patent's expiration, Teva has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

54. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '230 Patent.

55. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '230 Patent.

COUNT 5
Infringement of U.S. Patent 5,922,695 (ANDA No. 90-894)

56. Plaintiff repeats and repeats paragraphs 1-25 above as if set forth herein.

57. On information and belief, Teva submitted or caused to be submitted an ANDA, specifically ANDA No. 90-894, to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

58. On information and belief, ANDA No. 90-894 seeks approval to manufacture, use, sell and import tenofovir disoproxil fumarate for the purpose of treating HIV infection in adults.

59. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Truvada® Notice Letter"), Teva notified Plaintiff that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent.

60. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '695 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '695 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules

and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

61. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-20, 22-24, and 31 of the '695 Patent would not be infringed by the commercial manufacture, use, sale and importation of its proposed product that is the subject of ANDA No. 90-894.

62. By filing ANDA No. 90-894 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

63. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '695 Patent.

64. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 90-894 will infringe, induce infringement and/or contributorily infringe one or more claims of the '695 Patent.

COUNT 6
Infringement of U.S. Patent 5,935,946 (ANDA No. 90-894)

65. Plaintiff repeats and repeats paragraphs 1-25 and 57-58 above as if set forth herein.

66. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent.

67. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '946 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '946 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

68. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 Patent would not be infringed by the commercial manufacture, use, sale and importation of its proposed product that is the subject of ANDA No. 90-894.

69. By filing ANDA No. 90-894 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

70. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '946 Patent.

71. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 90-894 will infringe, induce infringement and/or contributorily infringe one or more claims of the '946 Patent.

COUNT 7
Infringement of U.S. Patent 5,977,089 (ANDA No. 90-894)

72. Plaintiff repeats and repeats paragraphs 1-25 and 57-58 above as if set forth herein.

73. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent.

74. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the

'089 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '089 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

75. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

76. By filing ANDA No. 90-894 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

77. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '089 Patent.

78. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil

fumarate for the use for which Teva seeks approval in ANDA No. 90-894 will infringe, induce infringement and/or contributorily infringe one or more claims of the '089 Patent.

COUNT 8
Infringement of U.S. Patent 6,043,230 (ANDA No. 90-894)

79. Plaintiff repeats and repeats paragraphs 1-25 and 57-58 above as if set forth herein.

80. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent.

81. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '230 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '230 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

82. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

83. By filing ANDA No. 90-894 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '230 Patent's expiration, Teva has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

84. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '230 Patent.

85. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 90-894 will infringe, induce infringement and/or contributorily infringe one or more claims of the '230 Patent.

COUNT 9
Infringement of U.S. Patent No. 5,922,695 (ANDA No. 91-215)

86. Plaintiff repeats and repeats paragraphs 1-25 above as if set forth herein.

87. On information and belief, Teva submitted or caused to be submitted an ANDA, specifically ANDA No. 91-215, to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

88. On information and belief, ANDA No. 91-215 seeks approval to manufacture, use, and sell tenofovir disoproxil fumarate for the purpose of treating HIV infection in adults.

89. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Atripla® Notice Letter"), Teva notified Plaintiff that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent.

90. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '695 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '695 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

91. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-

20, 22-24, and 31 of the '695 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-215.

92. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

93. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '695 Patent.

94. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use of which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement and/or contributorily infringe one or more claims of the '695 Patent.

COUNT 10
Infringement of U.S. Patent No. 5,935,946 (ANDA No. 91-215)

95. Plaintiff repeats and realleges paragraphs 1-25 and 87-88 above as if set forth herein.

96. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of

emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent.

97. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '946 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '946 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

98. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 90-215.

99. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

100. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '946 Patent.

101. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use of which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement and/or contributorily infringe one or more claims of the '946 Patent.

COUNT 11
Infringement of U.S. Patent No. 5,977,089 (ANDA No. 91-215)

102. Plaintiff repeats and repeats paragraphs 1-25 and 87-88 above as if set forth herein.

103. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent.

104. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '089 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '089 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a

Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

105. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

106. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

107. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '089 Patent.

108. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use of which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement and/or contributorily infringe one or more claims of the '089 Patent.

COUNT 12
Infringement of U.S. Patent No. 6,043,230 (ANDA No. 91-215)

109. Plaintiff repeats and realleges paragraphs 1-25 and 87-88 above as if set forth herein.

110. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent.

111. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '230 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '230 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

112. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

113. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets

containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '230 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

114. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '230 Patent.

115. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use of which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement and/or contributorily infringe one or more claims of the '230 Patent.

116. This case is an exceptional one, and Plaintiff is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(b) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §

355(j)) be a date which is not earlier than the expiration of the '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(c) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(d) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(e) A judgment declaring that the effective date of any approval of Teva's ANDA No. 90-894 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(f) A judgment declaring that the effective date of any approval of Teva's ANDA No. 90-894 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(g) A judgment declaring that the effective date of any approval of Teva's ANDA No. 90-894 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(h) A judgment declaring that the effective date of any approval of Teva's ANDA No. 90-894 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(i) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(j) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(k) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(l) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(m) A judgment declaring that the '695 Patent remains valid, enforceable and has been infringed by Teva;

(n) A judgment declaring that the '946 Patent remains valid, enforceable and has been infringed by Teva;

(o) A judgment declaring that the '089 Patent remains valid, enforceable and has been infringed by Teva;

(p) A judgment declaring that the '230 Patent remains valid, enforceable and has been infringed by Teva;

(q) A permanent injunction against any infringement of the '695 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(r) A permanent injunction against any infringement of the '946 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(s) A permanent injunction against any infringement of the '089 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(t) A permanent injunction against any infringement of the '230 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(u) A judgment that this is an exceptional case, and that Plaintiff are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(v) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '695 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(w) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '946 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(x) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '089 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

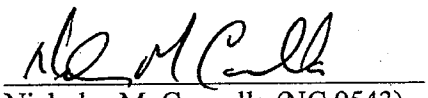
(y) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '230 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(z) Costs and expenses in this action; and

(aa) Such other relief as this Court may deem proper.

March 5, 2010

Respectfully submitted,



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